REMARKS

I. PRELIMINARY REMARKS

Claims 69, 70, 102 and 103 have been amended. Claims 104-107 have been added. No claims have been canceled. Claims 45, 47, 48, 50-54, 65, 68-71, 73-81, 83-87, 89, 90, 92-97 and 99-107 remain in the application. Reexamination and reconsideration of the application, as amended, are respectfully requested.

II. APPARENT REJECTION INCONSISTENCIES

Claims 53 and 54 have been rejected based on the combined teachings of Umeda and Matsuura. Claims 53 and 54 depend from independent claim 47. Independent claim 47 was not rejected based on the combined teachings of Umeda and Matsuura (or on Umeda or Matsuura individually) and, instead, was rejected based solely on Kovalcheck. The limitations of claim 47, which were necessarily part of claims 53 and 54, were also not discussed in the context of Umeda and Matsuura.[1] For purposes of this response and appeal if necessary, applicant will respond to the rejection as presented.

Claims 75-78 and 83-85 have been rejected based on the combined teachings of Umeda, Matsuura and Savage. Claims 75-78 depend from independent claim 45, while claims 83-85 depend from independent claim 52. Independent claims 45 and 52 were not rejected based on Umeda and Matsuura and, instead, were rejected based on Umeda and Lundquist. Here too, for purposes of this response and appeal if necessary, applicant will respond to the rejections as presented.

Clarification in an Office Action responsive to the amendments above and argument below is, however, respectfully requested.

[1] It should also be noted that the November 14, 2008 and July 21, 2009 Office Actions suffer from the same apparent defect, and that applicant has raised this issue twice previously without so much as an acknowledgment from the Examiner.

III. REJECTIONS UNDER 35 U.S.C. §§ 102 AND 103

A. The Rejections

Claims 47, 48, 50, 51, 65, 68, 80, 81, 87, 89 and 90 have been rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,472,017 to Kovalcheck ("Kovalcheck"). Claims 69, 70, 73, 74, 92-94, 99, 100, 102 and 103 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of Kovalcheck and U.S. Patent No. 5,507,725 to Savage ("Savage").

Claims 45, 52-54, 79 and 86 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of U.S. Patent No. 5,255,668 to Umeda ("Umeda") and U.S. Patent No. 5,848,986 to Lundquist ("Lundquist").

Claims 75-78 and 83-85 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of Umeda, U.S. Patent No. 6,450,948 to Matsuura ("Matsuura") and Savage.

Claims 71, 95, 96 and 101 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of Matsuura and Savage.

The rejections under 35 U.S.C. §§ 102 and 103 are respectfully traversed to the extent that they are applicable to the claims as amended above. Reconsideration thereof is respectfully requested.

B. The Cited References

Kovalcheck is directed to a deflectable catheter system 20 which includes an insertion tube 24 with a bendable portion 26. [Figure 2.] Turning to Figures 11 and 12, the bendable portion 26 includes a working channel 44, an outer covering 128 and a coil spring 132 located between the working channel 44 and the outer covering 128. The coil spring 132 has a proximal end 133 as well as tightly wound sections 134a-c that are respectively connected to two sets of pull wires 110a-c. A pair of splines 137, which are attached to the spring 132, ***are offset from the sets of steering wires 110a-c by 90 degrees***. To that

end, Kovalcheck indicates that the splines 137 "attach to the tightly wound section on both sides of the spring along the neutral axis" and "prevent compression of the coil spring 132 while ***adding negligible bending stiffness due to their position along the neutral axis***." [Col. 12, ll. 37-47.] In other words, the "neutral axis" is offset from the wires by pull wires 110a-c.

FIG. 11

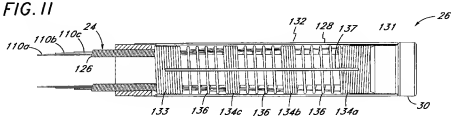
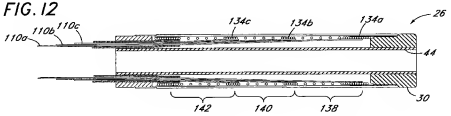
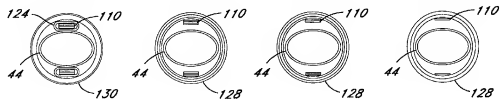


FIG. 12



To the extent that there is any question as to how Kovalcheck is using the word "neutral" in the context of bending, Kovalcheck includes the following description of Figures 10a-10d, "the working channel 44 lies centrally about a ***neutral bending plane, in this case, a horizontal plane, as the pull wires 110 are attached at top and bottom***." [Col. 11, ll. 10-13, emphasis added.]

FIG. 10a FIG. 10b FIG. 10c FIG. 10d



Finally, as noted in the Office Action, Kovalcheck describes an alternative embodiment:

> In an alternative embodiment, only one set of pull wires 110 can be used when a particularly large working channel 44 is required for certain applications. In this instance, the large channel 44 must be placed as far away from the point of connection of the pull wires 110 as possible to maximize the moment arm in order to successfully cause bending. Thus,

> there will only be ***one set of pull wires 110*** on one side of the insertion tube with the channel 44 on the opposite side and the controllably bendable section 26 will therefore be capable of ***deflection in only one direction***. Preferably, ***at least one axial spine must be attached along the length of the coil spring 32 in the neutral bending plane*** to prevent the spring from compressing on the side opposite the channel 44 when the wires are pulled.

[Col. 11, ll. 36-49, emphasis added.] In other words, like the embodiment illustrated in Figures 11 and 12, Kovalcheck is describing a spline that offset from the pull wire set by 90 degrees.

Umeda discloses a bending device that may be used in an endoscope or catheter. Referring to Figures 1 and 2, the illustrated endoscope includes a hollow body 1, with an insertion portion 2 and a bending portion 3, and a pair of wires 8a/8b that are used to deflect the bending portion. [Column 3, lines 28-32 and 56-65.] The bending portion 3 has a bending device 9. The bending device 9 includes a thin plate 10, a coil 20, a tip member 30, a connecting tube 40 that connects the coil to the tip member, and a connecting tube 50 that connects the coil to the insertion portion 2. The connecting tubes 40 and 50 include slits 42a/42b and 51a/51b for the thin plate 10. The connecting tube 40 also includes an extra set of slits 41a/41b that allow the distal ends of the wires 8a/8b to secured to the connecting tube 40. [Column 6, line 62 to column 7, line 7.]

Lunquist discloses medical probes with torque tubes that have flexible portions. Referring to Figures 3-5 and 21-22, the flexible portions 28 and 238 includes longitudinally spaced slots 30 and 240 that are ***perpendicular*** to longitudinal axis and terminate at the backbone wall portions 32 and 242. Steering wires 48 and 248 are located ***radially inward*** of the slotted flexible portions 28 and 238 (Figures 4 and 22).

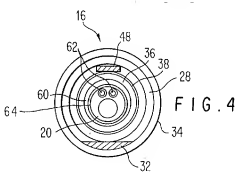


FIG. 4

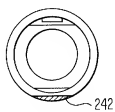


FIG. 22

Matsuura discloses a variety of deflectable tips for use with steerable surgical instruments. The instrument illustrated in Figures 1-5 includes a delectable tip section 40. The delectable tip section 40 includes proximal and distal collars 50A and 50B on opposite ends of a flexible tubular body 52. A pair of strengthening members 54 are positioned within the wall of the tubular body 52 and extend from the end collar 50A to the end collar 50B. The deflectable tip is illustrated in Figures 11 and 12 was also referred to in the Office Action. Here too, the deflectable tip includes collars 350A and 350B, a tubular body 352, and strengthening members 354A and 354B. Turning to Figure 22d, Matsuura also discloses that collars 1150A/1150B and ribs 1164 (in an alternative tip section) may be provided with grooves 1165 for a pull wire.

Savage discloses that certain structures (e.g. anchoring rings 22) may be located within a catheter wall. [Column 6, lines 16-61.]

C. Claims 45 and 75-79

1. The Claimed Combinations

Independent claim 45 calls for a combination of elements including, *inter alia*, "an elongate body defining a proximal portion and a distal portion," "a steering wire having a distal portion," "an anchoring member" and "means, directly connected to the anchoring member, for preventing compression …" and "a tubular member, that is a partial circle in cross-section and includes ***first and second longitudinally extending edges*** that together ***define a slot, which extends completely through the tubular member at the first and second edges, in which a portion of the steering wire is located*** …" The respective combinations defined by claims 75-79 include, *inter alia*, the elements recited in claim 45.

2. Discussion Concerning Claims 45 and 79 and the Rejection Based on Umeda and Lundquist

Umeda and Lundquist fail to teach or suggest the claimed combinations. For example, the Office Action asserted that (1) one of the Umeda wires 8a/8b corresponds to the claimed "steering wire," (2) a portion of the Umeda connecting tube 50 corresponds to the claimed "tubular member," and (3) the interior passage of connecting tube 50 corresponds to the claimed "slot," albeit one that is not "defined by first and second longitudinally extending edges."

Lundquist discloses slots 30 and 240 defined by edges that extend in a direction that is ***perpendicular to*** the longitudinal axis. In other words, the edges that define the Lundquist slots 30 and 240 do not extend longitudinally, they extend radially. The Lundquist steering wires 48 and 248 extend longitudinally and are located ***radially inward*** of the torque tube flexible portions 28 and 238 in a ***channel formed in the underlying*** tube 58 and tip 56 (or in the gape therebetween) in Figures 3-5 and a ***channel formed in the underlying cannula*** in Figures 21-22 (note col. 14, ll. 11-15).

Accordingly, even assuming that there was some reason to combine the Umeda and Lundquist teachings, the result is not the claimed combination. There simply is no slot defined by first and second longitudinally extending edges in which a steering wire is located.

As Umeda and Lundquist fail to teach or suggest the combination of elements recited in independent claim 45, applicant respectfully submits that the rejection of claims 45 and 79 under 35 U.S.C. § 103 should be withdrawn.

3. Discussion Concerning Claims 75-78 and the Rejection Based on Umeda, *Matsuura* and Savage

Dependent claims 75-78 depend from independent claim 45 and, accordingly, include the elements recited in claim 45. Applicant respectfully submits that (1) Umeda and ***Matsuura*** fail to teach or suggest the combination of elements set forth in claim 45 for the reasons presented in the arguments on pages 14-15 of the amendment filed

October 21, 2009, such arguments being incorporated herein by reference in the interest of brevity, and (2) that Savage fails to remedy the deficiencies in Umeda and Matsuura. As such, the rejection of claims 75-78 under 35 U.S.C. § 103 should also be withdrawn.

D. Claims 47, 48, 50, 51, 53, 54, 80 and 81

1. The Claimed Combinations

Independent claim 47 calls for a combination of elements including, *inter alia*, "an elongate body," "a stiffening member associated with the distal portion of the elongate body and located within the elongate body wall" and "an anti-tear device positioned within the elongate body wall." Claim 47 also indicates that "***the stiffening member and the distal portion of the steering wire are substantially diametrically opposed from one another***." The respective combinations defined by claims 48, 50, 51, 53, 54, 80 and 81 include, *inter alia*, the elements recited in claim 47.

2. Discussion Concerning Claims 47, 48, 50, 51, 80 and 81 and the Rejection Based on Kovalcheck

Kovalcheck fails to teach or suggest the claimed combinations. The Office Action has taken the position that one of the Kovalcheck pull wires 110a corresponds to the claimed "steering wire" and that one of the Kovalcheck splines corresponds to the claimed "stiffening member." [Office Action at pp. 2-3.] Even assuming for the sake of argument that this is a reasonable interpretation of the claims, there is no diametrically opposed pull wire 110a and spline.[2] To the contrary, each pull wire is offset by 90 degrees from the

[2] Applicant notes here that two elements are "diametrically opposed" if they are directed opposite each other on a circle, i.e. are on opposite ends of a diameter. Put another way, two elements are "diametrically opposed" if they are displaced from one another by 180 degrees about a circle. See also, footnote 1 of the Oct. 21, 2009 amendment and the exhibits referred to therein.

splines. Referring first to Figures 11 and 12, the splines 137 are on the neutral axis, i.e are offset from the two sets of pull wires by 90 degrees. Similarly, in the single set of pull wires embodiment described in column 11, lines 36-49, the spline is located in the neutral plane, i.e. offset from the set of pull wires by 90 degrees.

As Kovalcheck fails to teach or suggest each and every element of the combination recited in independent claim 47, applicant respectfully submits that the rejection of claims 47, 48, 50, 51, 80 and 81 under 35 U.S.C. § 102 should be withdrawn.

3. Discussion Concerning Claims 53 and 54 and the Rejection Based on Umeda and Lundquist

Dependent claims 53 and 54 depend from independent claim 47 and, accordingly, include the elements recited in claim 47. Thus, the combinations defined by claims 53 and 54 include, *inter alia*, "an anti-tear device positioned within the elongate body wall between the inner surface and the outer surface." The Umeda connecting tube 50, which page 14 of the Office Action identified as corresponding to the claimed "anti-tear device," is not located within a wall between the wall's inner and outer surfaces. Lundquist, which as cited for its slot teachings, fails to remedy this deficiency.

As Umeda and Lundquist fail to teach or suggest the combination of elements recited in independent claim 47, applicant respectfully submits that the rejection of claims 53 and 54 under 35 U.S.C. § 103 should be withdrawn.

E. Claims 52 and 83-86

1. The Claimed Combinations

Independent claim 52 calls for a combination of elements including, *inter alia*, "an elongate body," "a steering wire," "a stiffening member associated with the distal portion of the elongate body" and "a substantially c-shaped anti-tear device, including ***first and second longitudinally extending edges that together define a slot which extends***

completely through the tubular member at the first and second edges, associated with the stiffening member." Claim 52 also indicates that "a portion of the steering wire is positioned within the slot." The respective combinations defined by claims 83-86 include, *inter alia*, the elements recited in claim 52.

2. Discussion Concerning Claims 52 and 86 and the Rejection Based on Umeda and Lundquist

Umeda and Lundquist fail to teach or suggest the claimed combinations. For example, the Office Action asserted that (1) one of the Umeda wires 8a/8b corresponds to the claimed "steering wire," (2) a portion of the Umeda connecting tube 50 corresponds to the claimed "tubular member," and (3) the interior passage of connecting tube 50 corresponds to the claimed "slot," albeit one that is not "defined by first and second longitudinally extending edges."

Lundquist discloses slots 30 and 240 defined by edges that extend in a direction that is ***perpendicular to*** the longitudinal axis. In other words, the edges that define the Lundquist slots 30 and 240 do not extend longitudinally, they extend radially. The Lundquist steering wires 48 and 248 extend longitudinally and are located ***radially inward*** of the torque tube flexible portions 28 and 238 in a ***channel formed in the underlying*** tube 58 and tip 56 in Figures 3-5 and a ***channel formed in the underlying cannula*** in Figures 21-22 (note col. 14, ll. 11-15).

Accordingly, even assuming that there was some reason to combine the Umeda and Lundquist teachings, the result is not the claimed combination. There simply is no slot defined by first and second longitudinally extending edges in which a steering wire is located.

As Umeda and Lundquist fail to teach or suggest the combination of elements recited in independent claim 52, applicant respectfully submits that the rejection of claims 52 and 86 under 35 U.S.C. § 103 should be withdrawn.

3. Discussion Concerning Claims 83-85 and the Rejection Based on Umeda, ***Matsuura*** and Savage

Dependent claims 83-85 depend from independent claim 52 and, accordingly, include the elements recited in claim 52. Applicant respectfully submits that (1) Umeda and ***Matsuura*** fail to teach or suggest the combination of elements set forth in claim 52 for the reasons presented in the arguments on pages 17-18 of the amendment filed October 21, 2009, such arguments being incorporated herein by reference in the interest of brevity, and (2) that Savage fails to remedy the deficiencies in Umeda and Matsuura. As such, the rejection of claims 83-85 under 35 U.S.C. § 103 should also be withdrawn.

F. Claims 65 and 87

Independent claim 65 calls for a combination of elements including, *inter alia*, "an elongate body defining a proximal portion and a distal portion and including a wall defining an inner surface, an outer surface and a lumen," "a steering wire," "a stiffening member" and "an anti-tear device." Claim 65 also indicates that "***the steering wire … is substantially diametrically opposed to the stiffening member***." The combination defined by claim 87 includes, *inter alia*, the elements recited in claim 65.

Kovalcheck fails to teach or suggest the claimed combinations. The Office Action has taken the position that one of the Kovalcheck pull wires 110a corresponds to the claimed "steering wire" and that one of the Kovalcheck splines corresponds to the claimed "stiffening member." [Office Action at p. 4.] Even assuming for the sake of argument that this is a reasonable interpretation of the claims, there is no diametrically opposed pull wire 110a and spline. The splines 137 in the embodiment illustrated in Figures 11 and 12 are on the neutral axis, i.e are offset from the two sets of pull wires by 90 degrees. Similarly, in the single set of pull wires embodiment described in column 11, lines 36-49, the spline is located in the neutral plane, i.e. offset from the set of pull wires by 90 degrees.

As Kovalcheck fails to teach or suggest each and every element of the combination recited in independent claim 65, applicant respectfully submits that the rejection of claims 65 and 87 under 35 U.S.C. § 102 should be withdrawn.

G. Claim 68, 89 and 90

Independent claim 68 calls for a combination of elements including, *inter alia*, "an elongate body … including a wall defining an inner surface, an outer surface and a lumen," "a stiffening member associated with the distal portion of the elongate body" and "anti-tear means." Claim 68 also indicates that "the stiffening member and the distal portion of the steering wire ***are offset from one another by about 180 degrees*** about the longitudinal axis." The respective combinations defined by claims 89 and 90 include, *inter alia*, the elements recited in claim 68.

Kovalcheck fails to teach or suggest the claimed combinations. As noted in the preceding section, there is no diametrically opposed pull wire 110a and spline. The splines 137 in the embodiment illustrated in Figures 11 and 12 are on the neutral axis, i.e are offset from the two sets of pull wires by 90 degrees. Similarly, in the single set of pull wires embodiment described in column 11, lines 36-49, the spline is located in the neutral plane, i.e. offset from the set of pull wires by 90 degrees.

As Kovalcheck fails to teach or suggest each and every element of the combination recited in independent claim 68, applicant respectfully submits that the rejection of claims 68, 89 and 90 under 35 U.S.C. § 102 should be withdrawn.

H. Claims 69, 70, 73, 74, 92-94, 99, 100, 102 and 103

Independent claims 69 and 70 call for respective combinations of elements including, *inter alia*, "an elongate body defining … a distal portion and including a ***substantially solid single-piece*** wall defining an inner surface, an outer surface and a lumen," "a steering wire" and "an anchoring member located within the distal portion of the ***substantially solid single-piece*** elongate body wall between the inner surface and

the outer surface and secured to the steering wire." The combinations defined by claims 73, 74, 92, 99 102 and 103 include, *inter alia*, the elements recited in claim 69, and the combinations defined by claims 93, 94 and 100 include, *inter alia*, the elements recited in claim 70.

Kovalcheck and Savage fail to teach or suggest the claimed combinations. For example, to the extent that the Kovalcheck working channel 44 and the outer covering 128 (which is part of the bendable section 26 of the insertion tube 24) together form a wall, the wall is not a "substantially solid single-piece" wall. Not only do the Kovalcheck working channel 44 and outer covering 128 fail to define a "substantially solid single-piece" wall, Kovalcheck explicitly describes the reason for the two-piece design, i.e. it results in the working channel 44 being able to move longitudinally relative to the remainder of the insertion tube 24. [Col. 10, ll. 29-30.] It would not have been obvious, based on Savage, to convert the Kovalcheck bendable section 26 into a structure with a "substantially solid single-piece" wall because such a modification would destroy the relative movement functionality described in Kovalcheck.[3]

As Kovalcheck fails to teach or suggest each and every element of the respective combinations recited in independent claims 69 and 70, applicant respectfully submits that the rejection of claims 69, 70, 73, 74, 92-94, 99, 100 and 103 under 35 U.S.C. § 102 should be withdrawn.

I. Discussion Concerning Claims 71, 95, 96 and 101

Independent claim 71 calls for a combination of elements including, *inter alia*, "an elongate body defining … a distal portion and including a wall defining an inner surface, an outer surface and a lumen," "a steering wire" and "an ***anchoring member located within the distal portion of the elongate body wall between the inner surface and the outer surface*** and secured to the steering wire." The combinations defined by claims 95, 96 and 101 include, *inter alia*, the elements recited in claim 71.

The Office Action failed to establish a *prima facie* case of obviousness of the claimed combinations. For example, the Office Action asserted that (1) the Matsuura distal collar 50B (or 350B), which is not located within an elongate body wall, corresponds to the claimed "anchoring member" and (2) Savage would have suggested modifications to the Matsuura device that would have resulted in the Matsuura distal collar 50B (or 350B) being moved into an elongate body wall. Applicant respectfully submits that assertion (2) is incorrect. While it is true that Savage discloses the placement of various structures within an elongate body, none of those structures define the distal end of the device, as does the Matsuura distal collar. Accordingly, Savage would not have suggested moving the Matsuura distal collar into the elongate body wall.

Faced with deficiency in cited references, and in response to applicant's previous arguments, the Office Action proposed the following "reason" for modification of the Matsuura:

> [I] it is still the examiner's position that it would have been obvious to place a wall, however, thin or thick, around the device of Matsuura as this would strengthen the device in that it would provide a sort of "laminate" or "cover" that surrounds the bonding sites of 50a and 50b to 52. Without such a cover/wall/laminate, the bonding sites may be more likely to pull apart at their seams, and a cover/wall would provide an extra layer externally and internally which would reinforce these bonding sites/seams.

[Office Action at p. 19.] Applicant respectfully submits that the "reason" proposed in the Office Action is wholly unpersuasive because it ignores the fact that distal collar 50B is secured to the proximal collar 50A by a pair of strengthening members 54, which prevent the distal collar 50B (i.e. the structure at issue) and the adjacent tube 52 from being "pulled apart." The proposed modification would add complexity to the manufacturing process for what appears to be no beneficial result. The proposed modification would also result in either a reduction of thickness of the distal collar 50B, an increase in diameter of the device, or a reduction in the diameter of the internal lumen.

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[3] "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious." MPEP § 2143.01-VI.

As illustrated above, Matsuura and Savage fail to establish a *prima facia* case of obviousness with respect to the invention defined by independent claim 71. The rejection of claims 71, 95, 96 and 101 under 35 U.S.C. § 103 should, therefore, be withdrawn.

IV. NEWLY PRESENTED CLAIMS 104-107

Newly presented claims 104 and 105 depend from independent claim 45 and is patentable for at least the same reasons as claim 45.

Newly presented claims 106 and 107 depends from independent claim 52 and is patentable for at least the same reasons as claim 52.

V. CLOSING REMARKS

In view of the foregoing, it is respectfully submitted that the claims in the application are in condition for allowance. Reexamination and reconsideration of the application, as amended, are respectfully requested. Allowance of the claims at an early date is courteously solicited.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call applicant's undersigned representative at (310) 563-1458 to discuss the steps necessary for placing the application in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such

fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

Respectfully submitted,

May 21, 2010
Date

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